

K112955



JAN - 5 2012

510(k) Summary

510(K) Owner: Nova Biomedical Corporation

Registration Number: 1219029

Address: 200 Prospect St.
Waltham, MA 02454 USA

Phone: 781-894-0800

Fax Number: 784-891-4806

Contact Person: Paul W. MacDonald

Date Prepared: 30 Sept 2011

Proprietary Name: Nova StatStrip Lactate Hospital Meter System

Common Or Usual Name: Lactate Monitor

Classification Name: System, Test, Lactate

Product Codes: KHP, JJX

Predicate Device: K100602 - Nova StatStrip Lactate Hospital Meter System

Device Description: Nova StatStrip Lactate Hospital Meter System

Intended Use:	Indications for Use: The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.
Summary of Technological Characteristics:	The Nova StatStrip Lactate Hospital Meter System has the same fundamental scientific technology and intended use as the currently marketed Nova StatStrip Lactate Hospital Meter System (K100602). Both the Nova StatStrip Lactate Hospital Meter System and the proposed Nova StatStrip Lactate Hospital Meter System are hand held devices with similar intended use to quantitatively measure the lactate levels in whole blood. The principle of operation is the same for the proposed and predicate device. Each utilizes a test strip that is inserted into a meter for results within 13 seconds.
Comparison to Predicate Devices:	The proposed Nova StatStrip Lactate Hospital Meter System uses the same fundamental scientific technology, similar specifications, and has the same intended use as the predicate Nova StatStrip Lactate Hospital Meter System (K100602).
Performance Studies:	Laboratory testing was performed on the proposed Nova StatStrip Lactate Hospital Meter System. The laboratory studies demonstrated that the blood lactate results from the Nova StatStrip Lactate Hospital Meter System were substantially equivalent to the current methods for blood lactate measurements.
Conclusion:	Results of laboratory and clinical testing demonstrate that the performance of the Nova StatStrip Lactate Hospital Meter System has the same intended uses, with similar technological characteristics and can produce results that are substantially equivalent to results obtained on the predicate device. The system performs as intended and raises no new safety or effectiveness issues.

Comparison of Predicate Devices and Proposed device

Characteristic	Predicate K100602 - Nova StatStrip Lactate Hospital Meter System	Proposed Nova StatStrip Lactate Hospital Meter System
Measuring Range	0.7 – 20.0 mmol/L	0.3 – 20.0 mmol/L
Operating Principle	Electromechanical Biosensor Lactate oxidase (LOD)	Same
Intended Use	Indications for Use: The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.	Same
Sample type	Whole Blood	Same
Sample size	0.6 μ L	Same
Sample application	Capillary Draw	Same
Handheld meter?	Yes	Same
Meter Calibration	Automatic	Same
Data storage	1000 Patient Tests 200 QC Tests 4000 Operators	Same
Test Time	13 Seconds	Same
Weight	360 grams	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Nova Biomedical Corporation
c/o Paul W. MacDonald
Chief Quality & Regulatory Affairs Officer
200 Prospect St.
Waltham, MA 02454, USA

10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN - 5 2012

Re: k112955

Trade/Device Name: Nova StatStrip Lactate Hospital Meter System

Regulation Number: 21 CFR 862.1450

Regulation Names: Lactic Acid Test System

Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)

Product Code: KHP, JX

Dated: December 7, 2011

Received: December 9, 2011

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K112955

Device Name:

Nova StatStrip Lactate Hospital Meter System

Indications for Use:

Meter:

The Nova StatStrip Lactate Hospital Meter System is intended for in vitro diagnostic use by healthcare professionals for multiple patient use in a professional healthcare setting for clinical and for point-of-care usage for the quantitative determination of Lactate (Lac) in fresh venous and arterial whole blood specimens as an aid to evaluate the acid-base status of patients suspected of having lactic acidosis. It is not for use on capillary blood specimens. It is intended to provide plasma equivalent results to laboratory methods.

Test Strips:

Nova StatStrip Lactate Test Strips are intended for use only with the Nova StatStrip Lactate Hospital Meter for quantitative determination of lactate in fresh venous and arterial whole blood specimens. It is not for use on capillary blood specimens. The performance characteristics of the device for lactate measurements on capillary specimens have not been established. Nova StatStrip Lactate Test Strips are for testing outside the body (in vitro diagnostic use only).

Control and Linearity Solutions:

Nova StatStrip Lactate Control Solutions are intended for use with the Nova StatStrip Lactate Hospital Meter and Nova StatStrip Lactate Test Strips as a quality control check to verify the accuracy of blood lactate test results. There are 2 levels of controls, (Levels 1 and Level 2).

Nova StatStrip Lactate Linearity Kit solutions are used to check the linearity of the Nova StatStrip Lactate Hospital Meter. There are 4 levels of lactate linearity solutions: Level 1, Level 2, Level 3, and Level 4.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112955

Page 1 of _____